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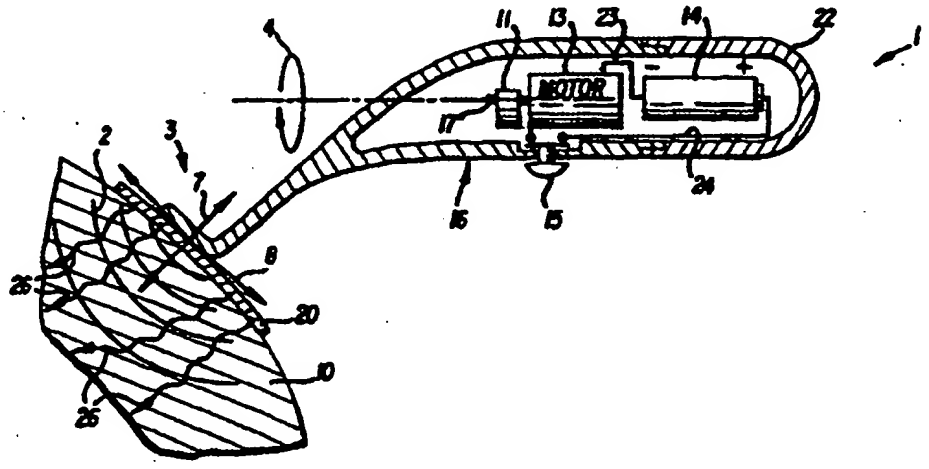
(54) Title: SONIC METHOD AND APPARATUS FOR COSMETIC APPLICATIONS



(57) Abstract

Sonic pressure is applied to the skin of sufficiently high intensity to cause sonic vibrations (2) within the skin. A therapeutic agent (20) is applied to skin either before or promptly after the sonic pressure waves are applied to the skin. The device (1) includes a rigid handle (16) and a flexible applicator (3). A motor (13) within the handle (16) has a weight eccentrically (11) mounted on the output shaft (17) thereof to cause rotary vibrations of the handle (16) about its central axis (4) which are translated into linear vibrations of the applicator (3). Sonic pressure waves are applied in repetitive burst type modality, and ultrasonic pressure waves may be applied between the bursts of sonic waves (2) to control the depth of penetration of therapeutic agents.

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SONIC METHOD AND APPARATUS FOR COSMETIC APPLICATIONS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to sonic devices for medical and cosmetic applications. More particularly the invention is concerned with methods and apparatus facilitating the use of sonic energy coupled to anatomical tissue to precondition the skin to allow the penetration of medical and cosmetic compounds, and to drive these compounds into and through the epidermis into the dermis. These compounds may be generally referred to as therapeutic agents.

Description of Prior Art

Numerous attempts have been made in the past to deliver medications and cosmetic compounds into the skin by chemical, electrical and ultrasonic means. The application of chemicals to modify the skin structure to allow the penetration of drugs was found to be dangerous because while it provided access for drugs to penetrate, it left the body unprotected against harmful environments. The application of electrical fields to create transient transport pathways by a method called electroporation, and the method to electrically charge drug molecules to increase their penetration through the skin called iontophoresis, have both been proven ineffective to deliver therapeutically adequate dosage of medications through the skin. Past applications of high frequency (0.5

to 3 megahertz) and high intensity (0.5 to 5 W/cm^2) therapeutic ultrasound, called sonophoresis, were found to be uncertain, inefficient, and the method found limited applications.

The efforts of the prior art of ultrasonically induced drug delivery (sonophoresis) which were focused on driving drug molecules through the skin by the applications of high (megahertz) frequency high energy ultrasonic pressure waves particularly suffered from the disadvantage of tissue heating and the associated modification and sometimes destruction of healthy cells. Once adequate ultrasonic power is applied either in a continuous wave ultrasonic modality, or maximum burst length that were practicable without adverse tissue heating effects to force cosmetic compounds through the highly resistive outermost sealing layer of the skin, the stratum corneum (SC), the cosmetic compounds will proceed uncontrollably through the less resistive dermis into the blood system, creating systemic absorption of the cosmetic compounds which is undesirable in most cosmetic applications.

What has occurred to date is that notwithstanding the teachings of the prior art, the ability to deliver large molecular weight cosmetic compounds, such as proteins, vitamins, moisturizers, etc., into the deeper layers of the skin remained unresolved.

SUMMARY OF THE INVENTION

Responding to the above described unresolved needs, the object of this invention is to provide a method and apparatus for the pre-treatment of the skin to open up passage ways through the epidermis to allow the penetration of therapeutic agents.

Another object of the invention is to provide a method and apparatus to enhance the penetration of therapeutic agents into the deeper layers of the skin, past the stratum corneum.

In the method of the invention, sonic pressure waves are applied to the skin of sufficiently high intensity to cause sonic vibrations within the skin. A therapeutic agent is applied to the skin either before or promptly after the sonic pressure waves are applied to the skin.

The apparatus of the invention includes a rigid handle portion and a flexible applicator portion. The handle portion supports means for producing vibrations which cause the applicator portion to vibrate in a linear manner so as to transmit sonic energy to the skin and cause sonic vibrations within the skin.

The depth of penetration of the therapeutic agent is controlled by applying sonic pressure waves in repetitive burst type modality, and ultrasonic pressure waves may be applied between the bursts of sonic waves.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a cross sectional view of the skin and the invention designed for developing passage ways in the stratum corneum and to enhance the penetration of therapeutic agents into the skin under the force of sonic pressure waves;

Fig. 2 shows a perspective view of the invention;

Fig. 3 shows the conversion of the rotational vibrations of the handle into linear vibrations of the flexible applicator tip, and the separation of the resulting linear vibrations into vibration vectors perpendicular and parallel to the skin; and

Fig. 4 shows a modified form of the invention.

DESCRIPTION OF THE PREFERRED METHODS AND EMBODIMENTS

Referring in detail to the drawings, the reference numerals herein refer to the like numbered parts in the drawings. In the following discussion, unless otherwise qualified, the term "sound" or "sonic waves" refer to either continuous sound waves or a repetitive burst type or pulsed sonic wave modality, and refer to audible frequency sound waves, typically at frequencies between 15 hertz to 25 kilohertz.

A sonic skin conditioning device **1**, in accordance with the simplest form of the present invention, is shown in FIG. 1. The skin conditioning device **1** comprises of a rigid handle **16** and a flexible applicator end **3**.

These components may be formed of plastic or metal and the like. The handle contains an electric motor **13** with a weight **11** mounted eccentrically on the rotatable output shaft **17** of the motor. The handle **16** has a removable end portion **22** which contains a replaceable battery **14**. The battery **14** is connected to the motor **13** via switch **15** and electrical conductors including lines **23** and **24**.

When the user energizes motor **13** by closing switch **15**, the motor **13** will rotate the eccentrically mounted weight **11** about the shaft **17**, generating rotary vibrations of the entire handle **16** about its central axis X as shown by arrow **4**. The flexible applicator end **3** is designed to resonate between about 15 hertz and 25 kilohertz, coinciding with the vibration frequency generated by the motor **13**. The vibrating flexible applicator end **3** acts as a transducer converting the rotary vibrations of the body **16** indicated by curving arrow **4** into linear vibrations of the applicator end **3** indicated by arrows **7** and **8**.

The outermost skin layer, the stratum corneum **10**, consists of flat dead cells filled with keratin fibers that are surrounded by ordered lipid bilayers. This ordered structure of the lipid bilayers normally provides an impermeable protection of the anatomy and prevents the entrance of medical and cosmetic compounds into the deeper layers of the skin. The linear vibration vector in the direction of arrow **7**, in frequencies between about 15 hertz and 25 kilohertz, creates corresponding frequency sonic

wave vibrations indicated by lines **2** in the stratum corneum **10**. The sonic wave vibrations **2** create physical vibrations which separate and disorganize the lipid bilayers. The disorganization of the lipid bilayers temporarily eliminates the barrier properties of the skin, and provides penetrable channels for medical and cosmetic compounds along paths indicated by arrows **26** through the epidermis into the deeper layers of the living skin and the underlying tissues. A body **20** of a therapeutic agent is shown in Fig. 1 as being disposed between the outer surface of the skin and the applicator portion of the skin conditioning device. Body **20** is applied to the skin manually, and then is engaged by the applicator portion so that the sonic pressure waves are applied through the therapeutic agent into the skin. In another method of the invention, sonic pressure waves are first applied to the skin to cause sonic frequency vibrations within the skin. The pressure waves are then terminated and a therapeutic agent is promptly applied to the skin before the natural function of the person's body decreases permeability of the skin.

Fig. 2 shows a perspective view of the invention to explain the conversion of the rotary vibration pattern of the handle **16** along the curved arrow **4** into the linear vibration patterns of the flexible applicator end **3** along the arrows **5** and **6**. The flexible applicator end **3** is designed to have a wide relatively inflexible dimension in the direction of arrow **5** and a thin, flexible dimension in the direction of arrow **6**. The thin section

of the flexible applicator end 3 is designed such a way that its natural resonant frequency coincides with the vibration frequency generated by the motor 13 and the eccentrically mounted weight 11 shown in FIG. 1. The vibration amplitude of the applicator end 3 is minimized in the direction of the thick dimension indicated by arrow 5, and maximized in the direction of the thin dimension indicated by arrow 6. It should be understood that the flexibility of applicator end 3 must be such that is capable of vibrating in the desired frequency range much in the same manner as a tuning fork.

Fig. 3 shows separation of the linear vibration of the flexible applicator end 3 in direction 6 into vibration vectors in the direction of arrow 7 perpendicular to the skin and the direction of arrow 8 parallel to the skin. The vibration vector perpendicular to the skin in direction 7 transfers the mechanical vibration into sound wave vibrations 2 in the tissues to disorder the lipid bilayers within the stratum corneum 10. The sound wave vibrations 2, sometimes called sonic pressure waves, also act to drive the therapeutic medical or cosmetic compounds into the deeper layers of the skin past the stratum corneum. The vibration vector parallel to the skin in direction 8 is utilized to spread the medical therapeutic or cosmetic compounds on the outer surface of the stratum corneum 10.

Refering to Fig. 4, a modified form of the skin conditioning device includes an applicator portion **32** having an inner end portion **34** which has a friction fit within a complementary recess within the handle. This arrangement enables the applicator portion of the device to be readily removed for cleaning or replacement when desired.

A method to control the penetration depth of therapeutic agents under the influence of sonic pressure waves was discovered by applying sonic pressure waves in a burst type modality. When the sonic pressure waves are applied in such a modality, for example, for one-tenth of a second, followed by a pause of nine-tenths of a second, the burst width is one-tenth of a second and the repetition time is one second. Therefore, the duty cycle is ten percent. The depth of penetration of therapeutic agents for a particular application frequency is proportional to the burst width of this frequency. When a burst is terminated and the sonic pressure waves are stopped, the molecules passing through the passageways will also stop. When the next burst is applied, it tends to introduce new molecules into the passage, finding channels which are still open rather than the partially blocked channels caused by the previously introduced molecules. Therefore, to limit the penetration depth of the therapeutic agents, very short, microseconds length bursts are applied. To deepen penetration, the burst width is increased, keeping molecules introduced into the passageways moving. The dosage delivered is

proportional to the sum of the sonic energy applied: Therefore, to deliver a particular dosage into the top layer of the skin, a large number of very short bursts are applied. To deliver the same dosage deep into the skin and into the underlying tissues, a smaller number but longer duration bursts are applied.

It was also discovered that high frequency ultrasonic waves in the megahertz frequency range tend to help the body reestablish the order of the lipid bilayers. This knowledge can be utilized to limit the penetration depth of the therapeutic materials under the influence of sonic pressure waves to the stratum corneum. In this enhanced method, short burst width pulsed modality sonic waves in the frequency range of 15 hertz to 25 kilohertz are applied to the skin to enhance the penetration of therapeutic agents, followed by the application of megahertz frequency low intensity noncavitating ultrasonic waves, instead of the pause described in the previous method above. The megahertz frequency range ultrasound produces gentle angstrom wavelength vibrations in the stratum corneum which tends to reorder the lipid bilayers, and contain the penetration of the therapeutic agents within the stratum corneum. A typical sequencing, for example, is one-tenth of a second low frequency (15 hertz to 25 kilohertz) sound wave burst followed by a nine-tenths of a second high frequency (megahertz frequency range) ultrasonic wave burst.

While the preceding description contains many specificities, these should not be construed as limitations on the scope of the invention, but rather as an exemplification of a preferred and additional embodiments thereof. Many other variations are possible. The important element of the method invented is the generation and application of linear vibrations perpendicular to the skin to generate sonic pressure waves toward the deeper layers of the skin past the stratum corneum. These linear vibrations can be generated by numerous ways other than conversion of a rotary vibration into linear vibration. For example, a piezoelectric transducer placed on the surface of the skin driven by a sonic frequency power supply could achieve the same result. Skilled artisans will readily be able to change dimensions, shapes and construction materials of the various components described in the preferred embodiment and adapt the invention to various types of applications. Accordingly, the scope of the invention should be determined not by the embodiments illustrated, but by the appended claims and their legal equivalents.

WHAT IS CLAIMED:

1. The method of facilitating the penetration of a therapeutic agent through a person's skin comprising, applying sonic pressure waves to the skin of sufficiently high intensity to cause sonic frequency vibrations within the skin thereby opening up passageways through the stratum corneum by disordering the lipid bilayers and increasing the permeability of the skin to allow the penetration of a therapeutic agent for a limited time period, terminating the application of sonic pressure waves to the skin, then promptly applying a therapeutic agent to the skin before the natural function of the person's body decreases the permeability of the skin and restores the normal environmental protection of the body.

2. The method as defined in claim 1 wherein the sonic pressure waves are applied in a repetitive burst type modality to reduce the tissue heating effects of the said sonic vibrations.

3. The method as defined in claim 2 wherein said bursts are repeated about every second with a burst width of about one-tenth of a second to provide a duty cycle of about ten percent.

4. The method of facilitating the penetration of a therapeutic agent through a person's skin comprising, applying a therapeutic agent to the skin, then applying sonic pressure waves through the therapeutic agent to the skin of sufficiently high intensity to force said therapeutic agent into the skin and concurrently cause vibrations in the skin thereby opening up passageways through the stratum corneum by disordering the lipid bilayers and increasing the permeability of the skin to allow the penetration of the therapeutic agent.

5. The method as defined in claim 4 wherein the sonic pressure waves are applied in a repetitive burst type modality to control the depth of penetration of the therapeutic agent.

6. The method as defined in claim 5 wherein said bursts are repeated about every second with a burst width of about one-tenth of a second to provide a duty cycle of about ten percent.

7. The method as defined in claim 5 wherein bursts of ultrasonic megahertz frequency low intensity noncavitating ultrasonic waves are applied to the skin between said bursts of sonic pressure waves.

8. An apparatus for facilitating the penetration of a therapeutic agent through a person's skin comprising, a rigid handle portion and a flexible applicator portion extending from the said rigid handle portion, said handle portion having a central axis, means located within said handle portion for creating a rotational vibration of said handle portion about its central axis, means to convert said rotational vibration of said handle into multidirectional linear vibrations of said flexible applicator portion which generate vibrations of sonic energy, said flexible applicator portion being operative to transmit said sonic energy through the dead outer surface of a person's skin into the underlying living tissue causing sonic frequency vibrations in the stratum corneum and underlying living tissue to open up passage ways for said therapeutic agents.

9. An apparatus as defined in claim 8 wherein the means located within said handle portion for creating a rotational vibration of said handle portion about its central axis comprises an electric motor having an output shaft, and means eccentrically mounted on said output shaft to generate rotary vibrations of the handle portion.

10. An apparatus as defined in claim 8 wherein the said flexible applicator portion is removable from the said rigid handle portion.

11. An apparatus as defined in claim 8 wherein said flexible applicator portion has a wide relatively inflexible dimension in one direction and a thin flexible dimension in another direction.

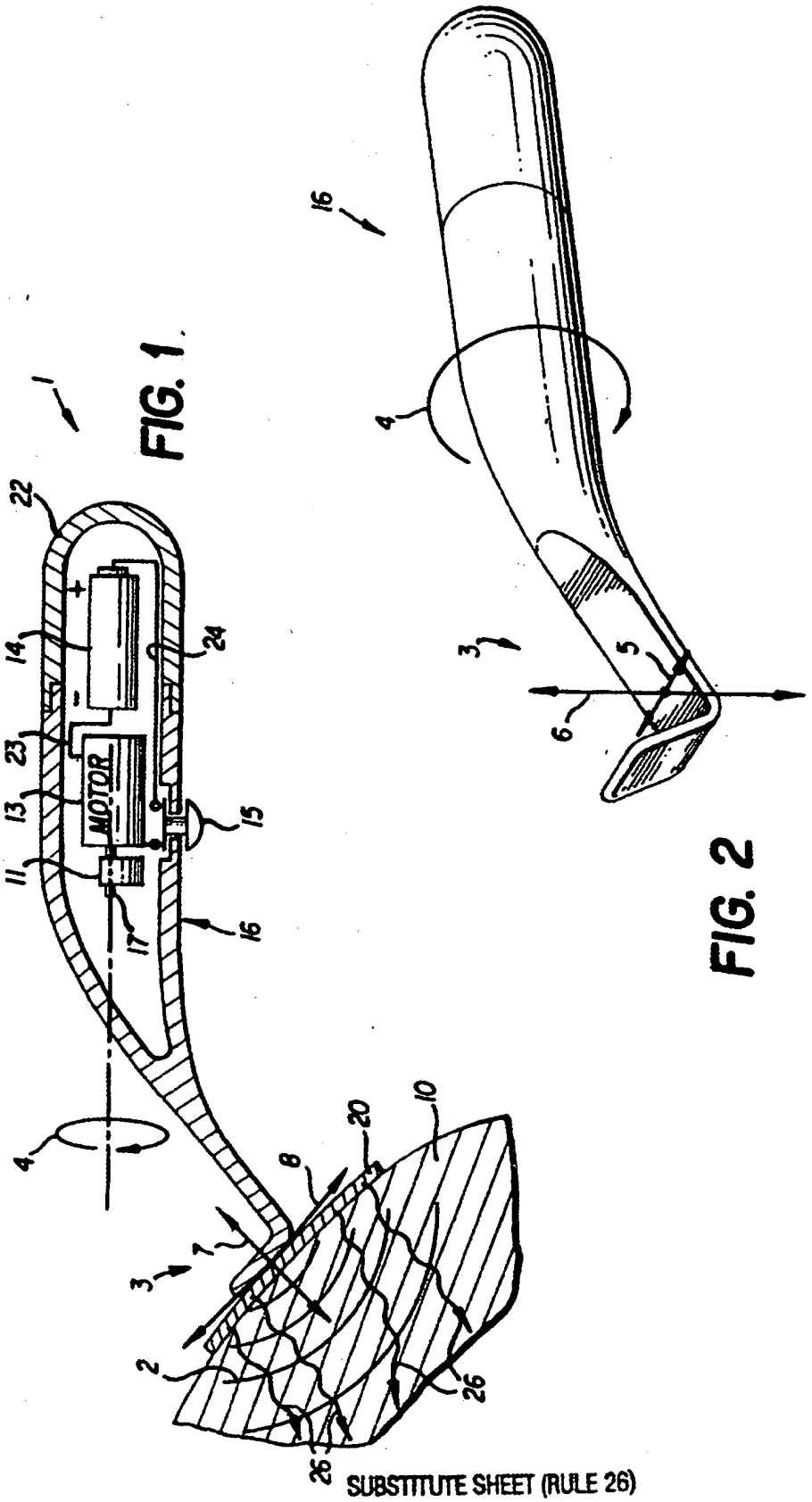

FIG. 1.

FIG. 2

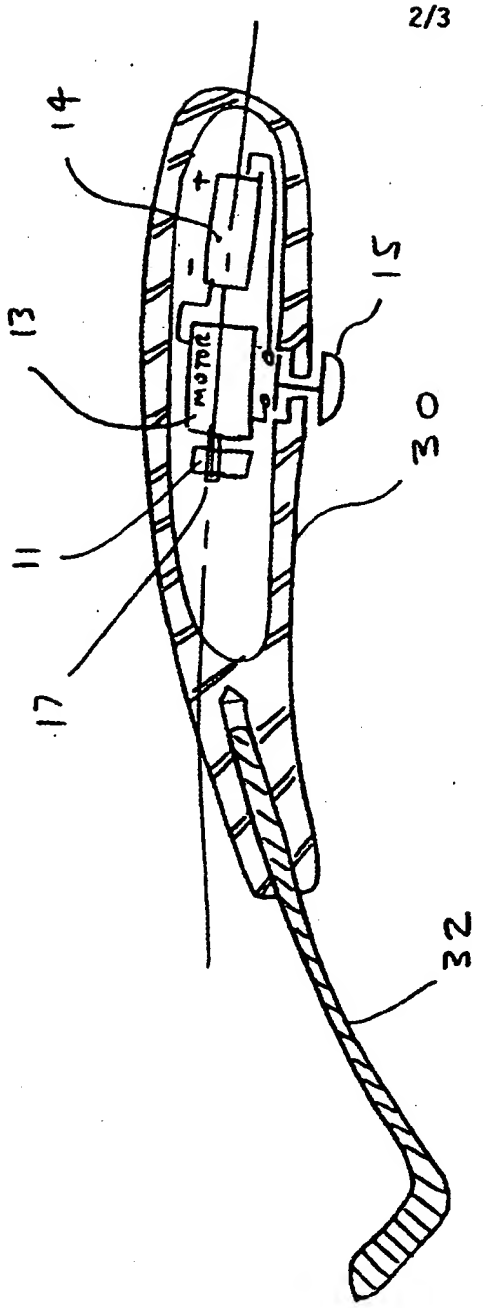

Fig. 4

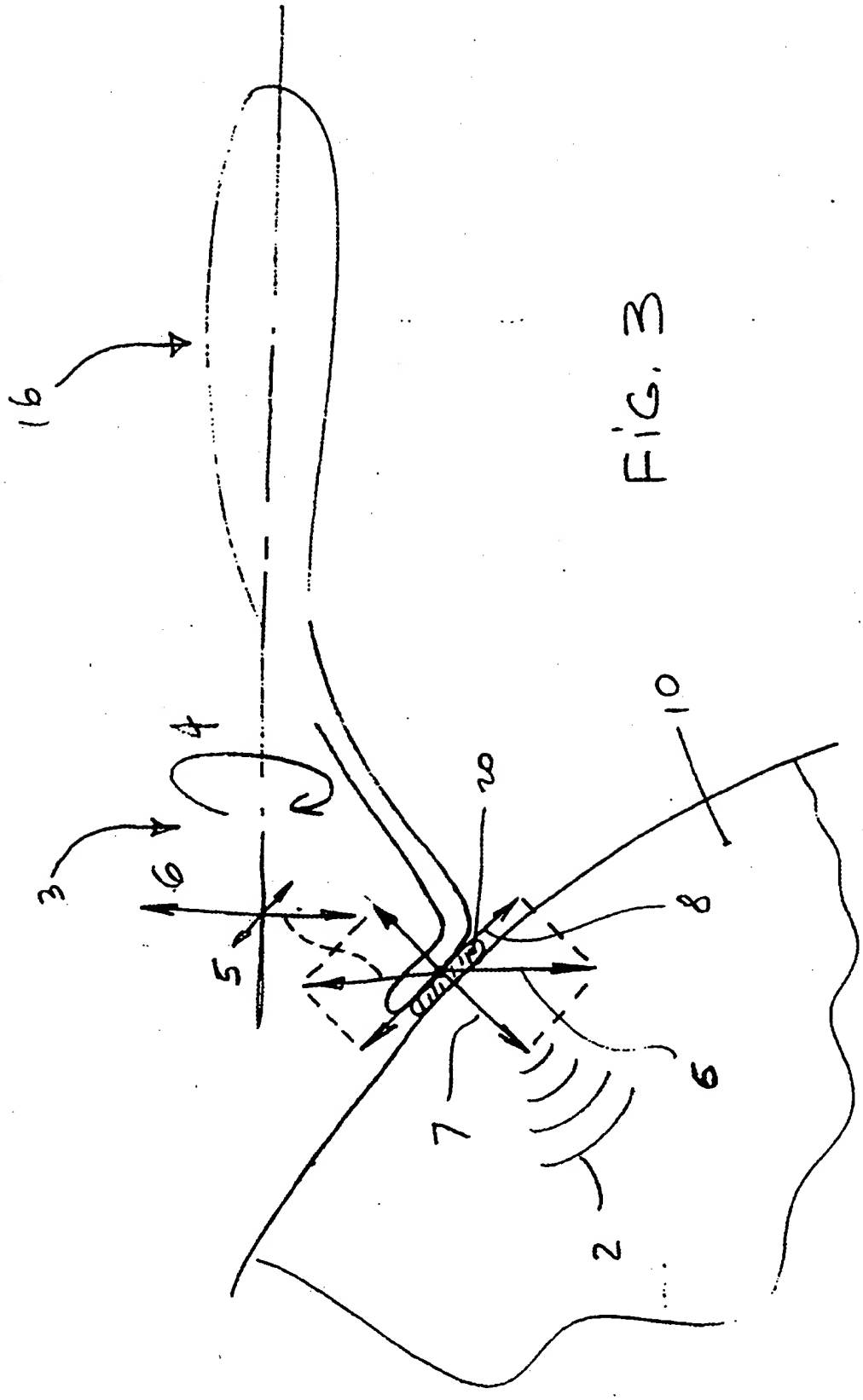

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20334

A. CLASSIFICATION OF SUBJECT MATTER

IPC( ) :A61H 01/00
US CL :601/72

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 601/17, 18, 46, 67, 69, 60, 72; 604/289, 290, 20; 607/108, 109

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
search terms: skin and (drug or medicine or therapeutic agent or agent), sonic and vibrat?.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5323769 A (BOMMANNAN et al) 28 June 1994, col. 1, line 11 to col. 10, line 3.	1-3
Y	US 4,787,888 A (FOX) 29 November 1988, entire document.	1-3

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 06 MARCH 1997	Date of mailing of the international search report 17 MAR 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer JUSTINE R. YU Telephone No. (703) 308-2675

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20334

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 4-11
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claims 4-10 are missing.

claim 11 depends on a missing claim 8.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.